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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/075,593	02/15/2002	Ellen M. Heath	GISM-P01-011	9392

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EXAMINER	
CHUNDURU, SURYAPRABHA	
ART UNIT	**PAPER NUMBER**
1637	

DATE MAILED: 11/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/075,593	HEATH ET AL.	
	Examiner	Art Unit	
	Suryaprabha Chunduru	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 August 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,9-17,19-28,30-38,40-49,51-59 and 61-65* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,9-17,19-28,30-38,40-49,51-59 and 61-65* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' response to the office action filed on January 15, 2004 and the supplemental response filed on July 29, 2004 have been entered and considered.

2. Claims 1-7, 9-17, 19-28, 30-38, 40-49, 51-59, and 61-65 are pending. Claims 8, 18, 29, 39, 50 and 60 are cancelled.

Response to arguments

3. Applicants response to the office action is fully considered and found to be persuasive in part.

4. With regard to the objections made in the previous office action, Applicants' amendment and arguments are fully considered and the objections are withdrawn herein in view of amendment.

5. With regard to the rejection made in the previous office action under 35 USC 112, second paragraph, Applicants' amendment and arguments are fully considered and the rejections are withdrawn herein in view of amendment.

6. A. With regard to the rejection made in the previous office action under 35 USC 102(e) as being anticipated by Heath et al., Applicants' arguments and amendment are fully considered and found persuasive, and the rejection is with drawn in view of the arguments and new grounds of rejections.

B. With regard to the rejection made in the previous office action under 35 USC 102(b) as being anticipated by Schneider et al., Applicants' arguments and amendment are fully considered and found persuasive and the rejection is with drawn in view of the arguments and new grounds of rejections.

C. With regard to the rejection made in the previous office action under 35 USC 102(b) as being anticipated by Gray et al., Applicants' arguments and amendment are fully considered and found persuasive and the rejection is with drawn in view of the arguments and new grounds of rejections.

D. Claims 1-4, 9-16, 24, 30-37, 45, 51-58 are rejected under 35 U.S.C. 102(b) as being anticipated by Henco et al. (USPN. 5, 057,426).

With reference to the instant claims 1-2, and 24, Henco et al. teach a method for isolating DNA from a biological sample wherein Henco et al. teach that the method comprises (a) separating the biological material comprising DNA from remainder of the biological sample (see column 11, lines 53-59, column 12, lines 20-25); (b) contacting the separated biological material comprising DNA with a hypertonic high salt solution so as to form a suspension of said biological material containing DNA (see column 10, lines 30-40, column 12, lines 26-32); (c) contacting the suspension with a cell lysis reagent to release DNA from non-DNA components (see column 11, lines 60-63); (d) physically separating DNA by centrifugation to yield isolated DNA (see column 11, lines 64-68, column 12, lines 1-15).

With reference to the instant claims 3-4, 9-16, 30-37, 51-58, Henco et al. also teach that (i) the method comprises biological material comprising bacterial cells, viruses, vegetable and animal tissue cells, body liquids (comprise blood) (see column 5, lines 10-21); lysis reagent comprises sodium dodecyl sulfate an anionic detergent greater than 0.1% w/v (see column 11, lines 60-63); (ii) high salt solution comprises sodium salts (3M sodium acetate) (see column 11, lines 63-67). Thus the disclosure of Henco et al. meets the limitations in the instant claims.

Response to arguments:

Applicants' arguments and amendment are fully considered and found not persuasive. Applicants argue that the instant invention is a sequential separation of DNA from biological material and argue that Henco et al. teach the lysis of the biological material first. These arguments are fully considered and found not persuasive because first, Examiner notes that the first lysis of biological material is to lyse cellular DNA and separate λ-phage DNA containing biological material from cellular DNA. Thus Henco et al. does teach sequential separation as shown in the example 2 (col. 12, lines 20-45) step (a) separation of DNA containing cells (λ-phage DNA containing biological material) from biological material (culture medium containing (λ-phage DNA /E.col cells) by centrifugation (see col. 12, line 20-25); step (b) contacting the separated biological material containing DNA (λ-phage DNA) with a high-salt solution (0.5 to 0.7 M NaCl) as discussed in the above rejection (see col. 12, line 26-32) wherein, this lysis step was used only to lyse cellular DNA, and not the λ-phage DNA; step (c) contacting the suspension with a lysis reagent (see col. 12, line 33-38) was used to lyse λ-phage DNA to release DNA from non-DNA biological components; step (d) separating (eluting) the DNA from non-DNA biological components in the lysate of step(c) to yield isolated DNA (see col. 12, lines 39-40). The instant claims are in "comprising" format and any additional components or steps can be included. Thus the instant claims do not prohibit a first lysis step. Thus the prior art anticipates the limitations in the instant claims and the rejection is maintained herein.

E. With regard to the rejection made in the previous office action under 35 USC 102(b) as being anticipated by Fairman, Applicants' arguments and amendment are fully considered and found persuasive and the rejection is with drawn in view of the arguments and new grounds of rejections.

7. With regard to the rejection made in the previous office action under 35 USC 103(a) as being unpatentable over Gray et al. in view of Heath et al., Applicants' arguments and amendment are fully considered and found persuasive and the rejection is with drawn in view of the arguments and new grounds of rejections.

New grounds of Rejections

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

A. Claims 1-3, 6-7, 9-10, 13-16, 19-21, 23-25, 27-28, 30-31, 34-37, 40-42, 44-46, 48-49, 51-52, 55-58, 61-63, 65 are rejected under 35 U.S.C. 102(b) as being anticipated by Miller et al. (Nucleic Acids Res., Vol. 16, No.3, 1988).

With reference to the instant claims 1-2, 24, 45, Miller et al. teach a method for isolating DNA from a biological sample comprising cells (whole blood) wherein Miller et al. disclose that the method comprises sequential steps:

(a) separating the biological material comprising DNA (white blood cells or buffy coats) from remainder of the biological sample (anticoagulated blood)(see page 1215, paragraph 2, lines 1-2);

(b) contacting the separated biological material comprising DNA with a hypertonic high salt solution (Nuclei lysis buffer containing 10mM Tris-HCl, 400 mM NaCl, and 2mM Na_2EDTA, pH 8.2) so as to form a suspension of said biological material containing DNA (see page 1215, paragraph 2, lines 2-4);

(c) contacting the suspension with a cell lysis reagent (1mg protease K in 1% SDS and 2mM Na_2EDTA) to release DNA from non-DNA components (see page 1215, paragraph 2, lines 4-7);

(d) physically separating DNA by precipitation to yield isolated DNA (see page 1215, paragraph 2, line 7-19).

With regard to claims 3, 6, 25, 27, 46, 48, Miller et al. teach that the biological sample is from whole blood (anticoagulated blood) (see page 1215, paragraph 2, line 1-2);

With regard to the instant claims 7, 28, 49, Miller et al. teach that the non-DNA biological component comprises protein (see page 1215, paragraph 2, line 10);

With regard to claims 9-10, 30-31, 51-52, Miller et al. teach that the hypertonic solution comprises sodium salt in an effective amount to precipitate proteins out of lysate (see page 1215, paragraph 1, lines 6-10, paragraph 2);

With regard to claims 19-20, 40-41, 61-62, Miller et al. teach that physically separating the DNA from lysate comprises precipitating non-DNA biological components from lysate by centrifugation without adding any additional reagents (see page 1215, paragraph 2);

With regard to claim 21, 42, 63, Miller et al. also teach isolated DNA is contacted with wash solution an alcohol to precipitate isolated DNA (see page 1215, paragraph 2);

With regard to claim 23, 65, Miller et al. teach that the isolated DNA is treated with a hydration reagent (TE buffer) (see page 1215, paragraph 2);

With regard to claims 13-16, 34-37, 55-58, Miller et al. teach that the lysis reagent comprises anionic detergent , sodium dodecyl sulfate with a concentration greater than 0.1% w/v (see page 1215, paragraph 2, line 4-6).

Thus the disclosure of Miller et al. meets the limitations in the instant claims.

B. Claims 1-3, 5-6, 13-17, 25-27, 34-38, 46-48, 55-59 are rejected under 35 U.S.C. 102(e) as being anticipated by Tomita (US 2003/0082616 A1).

With reference to the instant claims 1-2, 24, 45, Tomita et al. teach a method for isolating DNA from a biological sample comprising cells (whole blood) wherein Tomita et al. disclose that the method comprises sequential steps:

(a) separating the biological material comprising DNA (separating whole blood) from remainder of the biological sample (from a subject)(see page 8, paragraph 0073, line 1, paragraph 0047);

(b) contacting the separated biological material comprising DNA (whole blood) with a hypertonic high salt solution (NaCl) so as to form a suspension of said biological material containing DNA (see page 8, paragraph 0073, lines 1-4);

(c) contacting the suspension with a cell lysis reagent to release DNA from non-DNA components (see page 8, paragraph 0075-0076);

(d) physically separating DNA by precipitation to yield isolated DNA (see page 8, paragraphs 0077-0081).

With regard to claims 3, 5-6, 25-27, 46-48, Tomita et al. teach that the biological sample is from whole blood, bone marrow, biopsy tissue (see page 5, paragraph 0047);

With regard to claims 13-16, 34-37, 55-58, Tomita et al. teach that the lysis reagent comprises anionic detergent , sodium dodecyl sulfate with a concentration greater than 0.1% w/v (see page 8, paragraph 0075);

With regard to claims 17, 38, 59, Tomita et al. teach that the lysis buffer comprises RNase (see page 8, paragraph 0075).

Thus the disclosure of Tomita et al. meets the limitations in the instant claims.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 22, 43, and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller et al. (Nucleic Acids Res., Vol. 16, No.3, 1988) in view of Gray et al. (USPN. 5, 777, 098).

Miller et al. teach a method for isolating DNA from a biological sample comprising cells (whole blood) wherein Miller et al. disclose that the method comprises sequential steps:

(a) separating the biological material comprising DNA (white blood cells or buffy coats) from remainder of the biological sample (anticoagulated blood)(see page 1215, paragraph 2, lines 1-2);

(b) contacting the separated biological material comprising DNA with a hypertonic high salt solution (Nuclei lysis buffer containing 10mM Tris-HCl, 400 mM NaCl, and 2mM Na_2EDTA, pH 8.2) so as to form a suspension of said biological material containing DNA (see page 1215, paragraph 2, lines 2-4);

(c) contacting the suspension with a cell lysis reagent (1mg protease K in 1% SDS and 2mM Na_2EDTA) to release DNA from non-DNA components (see page 1215, paragraph 2, lines 4-7);

(d) physically separating DNA by precipitation to yield isolated DNA (see page 1215, paragraph 2, line 7-19).

Miller et al. also teach that the biological sample is from whole blood (anticoagulated blood) (see page 1215, paragraph 2, line 1-2); the non-DNA biological component comprises protein (see page 1215, paragraph 2, line 10); the hypertonic solution comprises sodium salt in

an effective amount to precipitate proteins out of lysate (see page 1215, paragraph 1, lines 6-10, paragraph 2); the physically separating the DNA from lysate comprises precipitating non-DNA biological components from lysate by centrifugation without adding any additional reagents (see page 1215, paragraph 2); isolated DNA is contacted with an alcohol to precipitate isolated DNA (see page 1215, paragraph 2); the isolated DNA is treated with a hydration reagent (TE buffer) (see page 1215, paragraph 2).

However, Miller et al. did not specifically teach contacting isolated DNA with a wash solution.

Gray et al. Gray et al. teach a method for DNA purification wherein Gray et al. teach that the method comprises (a) separating the biological material comprising DNA from remainder of the biological sample which includes contacting whole blood with a red blood lysis solution and separating white blood cells comprising DNA (see column 2, lines17-25, column 3, lines 1-21, column 7, lines 1-12); (b) contacting the separated biological material (white blood cells) comprising DNA with a hypertonic high salt solution so as to form a suspension of said biological material containing DNA (see column 4, lines 48-58); (c) contacting the suspension with a cell lysis reagent to release DNA from non-DNA components (see column 4, lines 34-36); (d) physically separating DNA by centrifugation to yield isolated DNA (see column 5, lines 1-11). Gray et al. also teach that physically separating the DNA from the lysate comprises precipitating DNA with an alcohol, followed by a wash solution (see column 5, lines 1-11).

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made, to combine a method of isolating DNA from a biological sample as taught by Miller et al. with an additional wash solution step as taught by Gray et al. to

achieve expected advantage of developing a enhanced method of extracting purified DNA because Gray et al. suggests that "the repeated wash steps would yield only the DNA without any contaminating reagents (see col. 5, line 3-11). It is further noted that selection of parameters such as additional wash solution step for routine optimization are explicitly recognized in Gray et al. As noted in *In re Aller*, 105 USPQ 233 at 235, More particularly, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. Routine optimization is not considered inventive and no evidence has been presented that the wash solution step performed was other than routine, that the products resulting from the optimization have any unexpected properties, or that the results should be considered unexpected in any way as compared to the closest prior art. An ordinary practitioner would have been motivated to combine the method of Miller et al. with the limitations such as additional the wash solution, as taught by Gray et al. for the purpose of reducing contaminating reagents, and to improve the quality and yield of the DNA.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion reached on 571-272-0782. The fax phone numbers for the organization where this application or proceeding is assigned are 703872-9306 for regular communications and - for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Suryaprabha Chunduru
November 10, 2004

JEHANNE SITTON
PRIMARY EXAMINER
11/10/04